



**Standard  
Process®**

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October 25, 1999



The Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street S.W.  
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Niacin and vitamin B6 are responsible for many important physiological processes concerned with physical and mental health and wellbeing.
- (2) Niacin is a co-enzyme essential for cell respiration, protein and carbohydrate metabolism, and lipid synthesis.
- (3) Vitamin B6 performs many important regulatory tasks inside the body, but its main responsibility is to break down and synthesize amino acids. In addition, vitamin B6 plays a predominant role in other metabolic and chemical processes that influence many important bodily functions. For example, vitamin B6 regulates and maintains the delicate fluid balance within the body, and assists in nervous and musculo-skeletal system functions by maintaining a proper sodium and potassium balance at the cellular level.
- (4) Niacinamide B6 supports immune and nervous system function.
- (5) The vitamin B6 portion of niacinamide enhances immune efficiency, aids in antibody production, and promotes red cell formation.
- (6) Niacinamide B6 influences cellular health.
- (7) Vitamin B6 is required to synthesize the important nucleic acids, RNA and DNA – the cells that carry genetic instructions for normal cellular growth and reproduction. Niacin is necessary to maintain healthy skin.

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- (8) Niacinamide B6 facilitates metabolic processes.
- (9) Niacin works to metabolize carbohydrates, fats, and proteins. Vitamin B6 is necessary for the production of hydrochloric acid and the proper absorption of fats and proteins.
- (10) Niacinamide B6 maintains a healthy circulatory system.
- (11) Niacin and vitamin B6 each have the ability to maintain healthy cholesterol levels in the blood. Niacin improves circulation. Vitamin B6 inhibits the formation of homocysteine, a toxic substance that attacks the heart muscle and deposits cholesterol around the heart muscle.
- (12) Liver and spleen are immense storehouses of vitamins and minerals and these ingredients are utilized because they not only are rich sources of nutrients, but also provides nutritional "stimulative" support to the corresponding organs in humans.
- (13) Whole desiccated animal tissue proteins provide nutrients and support the corresponding organs in humans.

These statements are made for a dietary supplement containing a proprietary blend of bovine liver, porcine stomach, calcium lactate, soy (bean), bovine spleen, ovine spleen, defatted wheat (germ), potassium para-aminobenzoate, bovine brain, and ascorbic acid. Other ingredients include gelatin, niacinamide, water, pyridoxine hydrochloride, and natural colors. The name of the product is Niacinamide B6.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden  
Standard Process Inc.

